（**FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !**）

HCG Lateral Flow Assay Kit

Catalog No: E-HD-C076-C

20T/40T

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

This kit contains colloidal gold labeled HCG monoclonal antibody I that is wrapped in conjugate pad, HCG monoclonal antibody II that is fixed on the membrane, and quality-control line C that is coated with goat anti mouse IgG antibody, adopt the highly specific antigen-antibody reaction and colloidal gold dry type immune chromatography technology, qualitatively determine HCG levels in human blood or urine.

Kit components

Item	Specification
Detection card	20/40 T
Whole blood buffer	1 Vials
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. Please read the manual carefully before use, changes of operation may result in unreliable results.
2. Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.
3. The detection card should be brought to room temperature before opening after take it out from the refrigerator. The opening detection card should be used as soon as possible.
4. Please do not use but not limited to the following liquids for negative control: Water, PBS.
5. The tested sample should be fresh and clear. Avoid of using samples of turbidity, polluted, high hemolysis or abnormal viscous.
6. Avoid of touching the chromatography membrane of the sample well and test well.
7. The waste of experiment should be considered as contaminant, and must be properly handled according to the local regulations.
8. The test environment should be kept at a fixed temperature to avoid testing at high temperatures.
9. Each reagent is optimized for use in the **E-HD-C076-C**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C076-C** with different lot numbers.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment, avoid freeze.

Expiry date: expiration date is on the packing box.

Sample preparation

1. Chorionic gonadotropin (HCG) test kit can be performed using serum, plasma, whole blood and urine.
2. Serum and plasma samples could be collected by conventional methods. After blood collection, serum and plasma should be immediately separated for analysis. EDTA or heparin sodium anticoagulant plasma could be used.
3. For serum or plasma, please determine within 4 hours after separation; If the sample cannot be tested within 4 hours, please store it at 2℃ - 8℃ for up to 5 days. The sample can be stored at -20℃ for at least 3 months.
4. After urine samples collection, it is recommended to complete the test within 4 hours. If the test cannot be finished within 4 hours, the urine samples can be stored for 2 days at 2℃ - 8℃, and should not be frozen.
5. Bring samples to room temperature prior to testing. Frozen serum or plasma samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

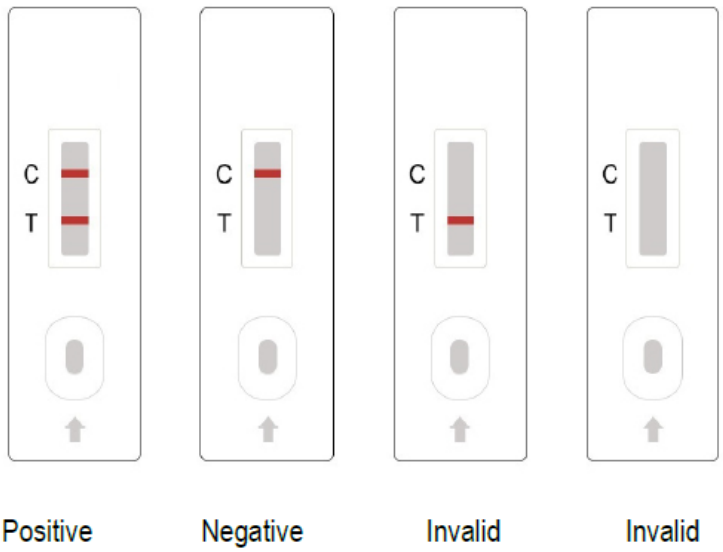
Assay procedure

Allow all kit components and sample to reach room temperature (25℃) prior to testing.

1. Before the test, the operation manual of the kit must be read completely. Before the test, the strip should be restored to room temperature (15℃-30℃). The test should be conducted at room temperature.
2. Take out the test card from the aluminum foil packaging bag, place it on a horizontal, dry plane, and use it within 1 hour after unsealing to prevent moisture of test card.
3. Add samples: accurately draw 100 μL serum, plasma and urine samples and add them vertically into sample well, and start the timer. Or add 100 μL of whole blood samples into sample well, then add 1 drop of whole blood buffer as soon as possible and start the timer.
4. Interpretation: at 5 minutes, observe the color rendering and interpret the result qualitatively. The result is valid within 15 minutes, read results after 15 minutes is invalid.

Judgment of result

1. **Positive:** Both the test line (T line) and the quality control line (C line) appear colors.
2. **Negative:** The test line (T line) does not appear color, only the quality control line (C line) appears color.
3. **Invalid:** The quality control line (C line) does not appear color, which means that the test is invalid and the test should be repeated.



NOTE: This figure is only used as a reference.

Limitations of this test method

1. This reagent is only used for the detection of human serum, plasma, whole blood and urine samples. The correct results can only be obtained by careful operation in strict accordance with the operating procedures. Any modification to the operating procedures may affect the results.

2.The test result of this reagent can only be used as a doctor or other diagnostic auxiliary tool. The test result should be combined with other clinical and laboratory data. If the test result is inconsistent with the clinical evaluation, further examination is needed.

3.False positive results can be caused by several factors: cross-reaction of similar antibody components in the samples; some of the nonspecific components in the samples have similar antigen epitope capture labeled antibodies.

4.False negative results may be due to the following reasons: some unknown components blocked antigen epitope to prevent it from binding to the antibody; unstable antigens gradually degrade with time and temperature and cannot be recognized by antibodies. Unreasonable sample collection, transshipment and treatment resulted in too low concentration of the substance in the sample. Effective test results depend on a good kit sample storage environment.

5.Other factors can also cause test errors, including technical reasons, operational errors, and other sample factors.

6.Hemoglobin, triglyceride and bilirubin in the samples all interfere with the test results, and the maximum allowable concentrations of hemoglobin is 5g/L, triglyceride is 25g/L and bilirubin is 0.1g/L, respectively.